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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
WHISENANT, ETHAN C	

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1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,963	LEXOW, PREBEN	
	Examiner	Art Unit	
	Ethan Whisenant	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26, 29-35 and 40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,29-35 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/886,223.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

NON-FINAL ACTION

►The applicant's response (filed 18 MAY 09) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 26, 29-35 and 40** is/are pending. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

35 USC § 102

►The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
> or
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

►The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

CLAIM REJECTIONS UNDER 35 USC § 102

► **Claim(s) 26, 29-35 and 40** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Brenner [US 5,552,278 (1996)].

Please note that Brenner teach multiple embodiments including :
Embodiment 1 : The embodiment described in Example 1, Columns 16-17 . All of the rejections which follow rely on this embodiment disclosed by Brenner.

Claim 26 is drawn to a method of sequencing all or part of a target nucleic acid molecule which comprises three required steps. To begin, a portion of said target nucleic acid molecule is determined. Next, the position of said potion within said target nucleic acid molecule is determined wherein this second step is carried out by identifying a label which is incorporated into or onto said portion of said target nucleic acid molecule and which indicates the position of said portion within said target nucleic acid molecules. Finally, the information obtained in step 1 and 2 are combined to obtain the sequence of all or part of said target nucleic acid molecule.

Brenner teach a method of sequencing all or part of a target nucleic acid molecule which comprises all of the limitations recited in Claim 26. See, for example Example 1 which begins in Column 16. Embodiment 1of Brenner meet all of the limitations recited in Claim 26.

Claim 29 is drawn to an embodiment of the method of Claim 26 wherein the portion which is sequenced has 4 or more nucleotide bases and/or the position of said portion within said target molecule is determined with an accuracy of less than 1 kb.

Brenner teach this limitation in that Brenner teach using their method to identify the position and identity of single nucleotides within a target molecule (i.e. the position of said portion within said target molecule is determined with an accuracy of less than 1

kb). Embodiment 1 of Brenner meet all of the limitations recited in Claim 29, see Example 1 which begins in olumn 16.

Claim 30 is drawn to an embodiment of the method of Claim 26 wherein said portion is sequenced by identifying magnifying tags associated with the target nucleic acid molecule, wherein said magnifying tags correspond to one or more bases of an adapter binding region or to one or more bases in proximity to an adapter binding region, wherein said adapter binding region binds an adapter molecule which comprises: (i) one or more of said magnifying tags, or (ii) a means for attaching one or more of said magnify tags.

Embodiment I Brenner teach this limitation. Brenner teach using their method to identify the position and identity of a sequence of nucleotides within a target molecule by identifying which label (i.e. magnifying tag) is attached to the probe. Furthermore, the labeled probes (i.e. the magnifying tags of Brenner/Embodiment 1) correspond to one or more bases of an adapter binding region or to one or more bases in proximity to an adapter binding region, wherein said adapter binding region binds an adapter molecule which comprises: (i) one or more of said magnifying tags, or (ii) a means for attaching one or more of said magnifying tags. See, for example, Example 1, the description of which begins in Column 16.

Claim 31 is drawn to an embodiment of the method of Claim 26 wherein the sequence of said target nucleic acid molecule is determined by assessing the complementary (i.e. ?complementarity?) of a portion of said target nucleic acid molecule by a process comprising the steps of (i)treating said target nucleic acid molecule so that at least a region of said target nucleic acid molecule is converted into a form suitable for binding a complementary probe, wherein said complementary probe is bound to a solid support or said complementary probe carries a means for attaching to a solid support; (ii) binding said complementary probe to at least a portion of said region suitable for binding a complementary probe; (iii) optionally repeating steps (i) and (ii),

with the *proviso* that said complementary probe binds to an adjacent or overlapping region of said target nucleic acid molecule relative to the region to which the complementary probe of the previous cycle bound; and (iv) determining the sequence of said target nucleic acid molecule by identifying the complementary probe(s) to which said target nucleic acid molecule bound.

At least, Embodiment I of Brenner teach this limitation. In Brenner Embodiment I the target nucleic acid molecule is treated so that at least a region of said target nucleic acid molecule is converted into a form suitable for binding a complementary probe. Said form being a single stranded region to which a labeled complementary probe binds. Furthermore, Brenner Embodiment I teaches binding a complementary probe to the region suitable for binding a complementary probe (i.e. the 5' overhang of the target nucleic acid molecule). Brenner Embodiment I also teaches optionally repeating steps (i) and (ii), with the *proviso* that said complementary probe binds to an adjacent or overlapping region of said target nucleic acid molecule relative to the region to which the complementary probe of the previous cycle bound; and finally Brenner Embodiment I teach step (iv) determining the sequence of said target nucleic acid molecule by identifying the complementary probe(s) to which said target nucleic acid molecule bound.

As regards the limitation in Claim 31 which requires that the complementary probe be bound to a solid support or said complementary probe carry a means for attaching to a solid support. Brenner Embodiment I meets these limitations in that during the method a distinctly labeled complementary probe specifically hybridizes to the target nucleic acid molecule which is immobilized on a solid support thus the complementary probe(s) become bound to a solid support by complementary binding to the target. The means for attaching to a solid support being the four base 3' overhang of the labeled complementary probe.

Claim 32 is drawn to an embodiment of the method of Claim 31 wherein in step (i) is a single stranded nucleic acid molecule.

Embodiment I of Brenner, teach this limitation. See Example I which begins Column 16. Note the -4 target polynucleotide which following enzymatic treatment comprising a four base single stranded region which ultimately hybridize to one of four probes shown in Column 16.

Claim 33 is drawn to an embodiment of the method of Claim 31 wherein in step (ii) said portion is 4 to 12 nucleotide bases in length

Embodiment I of Brenner, teach this limitation. See Example I which begins Column 16. Note the -4 target polynucleotide which following enzymatic treatment comprising a four base single stranded region (i.e. a portion which is 4 to 12 nucleotide bases in length)

Claim 34 is drawn to an embodiment of the method of Claim 26 wherein a portion of said sequence is determined by identifying magnifying tags associated with the target nucleic acid molecule, wherein said magnifying tags correspond to one or more bases of an adapter binding region or to one or more bases in proximity to an adapter binding region, wherein said adapter binding region binds an adapter molecule which comprises:(i)one or more of said magnifying tags, or
(ii) a means for attaching one or more of said magnifying tags; and an adjacent or overlapping portion of said sequence is determined by a process comprising the steps of: (i) treating said target nucleic acid molecule so that a region of said target nucleic acid molecule is converted into a form suitable for binding a complementary probe, wherein said complementary probe is bound to a solid support or said complementary probe carries a means for attaching to a solid support; (ii) binding said complementary probe to at least a portion of said region suitable for binding a complementary probe; (iii) optionally repeating steps (i) and (ii), with the *proviso* that said complementary probe binds to an adjacent or overlapping region of said target nucleic acid molecule

relative to the region to which the complementary probe of the previous cycle bound; and (iv) determining the sequence of said target nucleic acid molecule by identifying the complementary probe(s) to which said target nucleic acid molecule bound.

Brenner, teach this embodiment. See Example 1 in Columns 16-17 (Embodiment I of Brenner). As regards the limitation in Claim 34 which requires that the complementary probe be bound to a solid support or said complementary probe carry a means for attaching to a solid support. Brenner Embodiment I meets these limitation in that during the method a distinctly labeled complementary probe specifically hybridizes to the target nucleic acid molecule which is immobilized on a solid support thus the complementary probe(s) become bound to a solid support by complementary binding to the target. The means for attaching to a solid support comprising the four base 3' overhang of the labeled complementary probe.

Claim 35 is drawn to an embodiment of the method of Claim 26 wherein said method is performed on a sample comprising a heterogeneous mixture of target nucleic acid molecules

Brenner, teach this limitation. See Column 13, lines 40-52.

Claim 40 is drawn to an embodiment of the method of Claim 26 wherein said magnifying tags comprise a nucleic acid sequence of at least two nucleotide bases

Brenner, teach this limitation. Note the labeled complementary probe in Column 16.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

►Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are not deemed to be persuasive. The applicant has traversed the rejection of Claim 39 (i.e. Claim 26 as currently amended) arguing that Brenner fails to teach all of the limitations recited in Claim 26 (amended), in that Brenner fails to teach "the step of identifying the label, which is incorporated into or onto the portion of the target nucleic acid molecule, so as to determine the position of the portion within the target nucleic acid. In other words the applicant argues, Brenner fails to teach "determining the position of a portion within a target nucleic acid molecule by identifying a label which is incorporated into or onto the portion of the target nucleic acid molecule". The examiner respectfully disagrees. Brenner clearly teach identifying a label which allows for (i.e. indicates) determining the position of a portion within a target nucleic acid molecule by identifying a label which is incorporated into or onto the portion of the target nucleic acid molecule". See especially Example I. The label on the labeled complementary probes shown in Column 16 are incorporated into or onto the target nucleic molecule and indicates the identity of said portion and the position of said portion within the target nucleic acid molecule.

CONCLUSION

►**Claim(s) 26, 29-35 and 40** is/are rejected and/or objected to for the reason(s) set forth above.

►Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM

EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz, can be reached at (571) 272-0763.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/
Primary Examiner
Art Unit 1634

EXAMINER SEARCH NOTES

27 AUG 09 - ECW

Databases searched: USPATFULL, USPG-PUBS, JAPIO and EUROPATFULL via EAST &

CAplus, Medline and BIOSIS via STN

Reviewed the parent(s), if any, and any search(es) performed therein : see the BIB data sheet

Reviewed, the search(es), if any, performed by prior examiners

Search terms:

Inventor(s) : e.g. Lexow P?/au

Sequence or Sequencing
Nucleic
Magnifying tag$
Label or labeled
Cycle or cycles

Brenner S?/au